Michigan Department of Agriculture

Training Program for the Professional Food Service Sanitarian

Module 8: A HACCP Principles Guide for Operators of Food Establishments at-the Retail Level

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Introduction

Purpose and Scope

This Guide has been prepared by the United States Food and Drug Administration (FDA) based on input from state and local regulators, industry, academia, and consumers for the purpose of assisting operators and employees of food establishments at the retail level in their efforts to produce safe food. The portion of this Chapter "Defining Retail" is included to further describe the Scope of this Guide. Within this document, facilities that are considered in its scope are referred to either as "food establishments" or "retail food establishments."

This document is intended to serve as a guide in the writing of a simple plan based on HACCP principles that can be used to manage food safety. It is very important to understand that this Guide is intended to assist industry's voluntary implementation of HACCP principles. It is not meant to stand alone, but instead should be used together with advice from and in consultation with your federal, state, local, or tribal food safety regulatory authority. Your regulatory authority is an important resource for reviewing your food safety management system. Regulatory food safety professionals can provide important information for the public health rationale for controlling a particular hazard. Users of this document also need to consult and use the latest edition of the FDA Food Code since many of its requirements are not reproduced here but constitute a fundamental program that is prerequisite to implementing a HACCP program. If you do not have a copy of the Food Code, refer to Chapter 6, FDA Publications & Federal Regulations, p. 62, for information on how to obtain a copy.

Background

Hazard Analysis Critical Control Point (HACCP) is a common sense technique to control food safety hazards. It is a preventive system of hazard control rather than a reactive one. Food establishments can use it to ensure safer food products for consumers. It is not a zero risk system, but is designed to minimize the risk of food safety hazards. HACCP is not a stand alone program but is one part of a larger system of control procedures that must be in place in order for HACCP to function effectively. These control procedures are prerequisite programs and are discussed more in Chapter 4.

The success of a HACCP program is dependent upon both people and facilities. Management and employees must be properly motivated and trained if a HACCP program is to successfully reduce the risk of foodborne illness. Education and training in the principles of food safety and management commitment to the implementation of a HACCP system are critical and must be continuously reinforced. Instilling food worker commitment and dealing with problems such as high employee turnover and communication barriers must be considered when designing a HACCP plan.
Successful implementation of a HACCP plan is also dependent upon the design and performance of facilities and equipment. The likelihood of the occurrence of a hazard in a finished product is definitely influenced by facility and equipment design, construction, and installation which play a key role in any preventive strategy.

> "Both parts of HACCP - the hazard analysis and the critical control points - are influenced by the design of equipment and structures in retail food establishments.... Facility and process designs can help a HACCP system be more effective by preventing cross contamination and meeting Standard Operating Procedures (SOPs), therefore allowing the hazard analysis to focus on significant hazards associated with the food itself."
>
> (Comments made by FDA HACCP Policy Strategic Manager, Dr. John Kvenberg, on June 24, 1996 to the Institute of Food Technologists' seminar on Legal Constraints in Facility/Process Design).

Risks Associated with Foods

As stated in the Food Code:

> "Foodborne illness in the United States is a major cause of personal distress, preventable death, and avoidable economic burden., In 1994, the Council for Agricultural Science and Technology estimated 6.5 to 33 million people become ill from microorganisms in food, resulting in as many as 9, 000 needless deaths every year... The Centers for Disease Control and Prevention (CDC) have consistently stated that where reported foodborne outbreaks were caused by mishandling of food, most of the time the mishandling occurred within the retail segment of the food industry ... where ready-to-eat food is prepared and provided to the public for consumption. "

Because many foods are agricultural products and have started their journey to your door as animals and plants, raised in the environment, they may contain microscopic organisms. Many foods contain nutrients that make them a place where microorganisms can live and even grow. Some of these organisms are pathogens, which means that under the right conditions and in the right numbers, they can make someone who eats them ill. Raw animal foods such as meat, poultry, fish, and eggs often carry bacteria, viruses, or parasites that can be harmful to humans. Also because foods are from the environment, they can contain objects such as stonesthat could cause injury. Food may be contaminated naturally, for example from the soil in which it is grown or because of harvest, storage, or transportation practices. Some foods undergo further processing and at times, despite best efforts, become contaminated. These inherent hazards, along with the hazards that may occur in your establishment, such as metal fragments from grinding, can lead to injury, illness, or death.

Hazards include:

Biological concerns, such as:

- bacterial, parasitic, or viral contamination
- bacterial growth
- bacterial, parasitic, or viral survival
- bacterial toxin production
- bacterial, parasitic, or viral cross-contamination

Physical objects

- Stones
- Glass
- metal fragments
- packaging materials

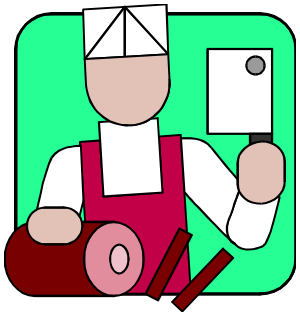
Chemical contamination

- nonfood-grade lubricants
- cleaning compounds
- food additives
- insecticides

In a report from CDC titled, Surveillance for Foodborne Disease Outbreaks - United States, 1988-1992, it is clear that **bacterial agents are the leading cause of laboratory-confirmed outbreaks** and that the main reasons for the outbreaks are:

improper holding temperatures
poor personal hygiene
improper cooking temperatures
foods from unsafe sources, and
contaminated equipment.

Defining Retail



As stated in Chapter 1, Introduction, this document uses the terms "food establishments" and "retail food establishments" interchangeably. For a definition of a "food establishment" refer to Chapter 5 - Glossary.

Unlike industries such as canning, other food processing, and dairy plants, the "retail" industry is not easily defined by specific commodities or conditions. The following is a partial listing of the types of businesses that are usually considered part of the retail food industry. There are many situations which may include more than one type of operation.

back-country guided trips for groups	bakeries
bars and taverns	bed and breakfast operations
cafeterias	camps -recreational, children's, etc.
casinos	child and adult day care
church kitchens	commissaries
community fund raisers	convenience stores
fairs	food banks
grocery stores with specialized departments	deli in-store prepared foods
health care facilities	interstate conveyances
mail order foods	markets
meal services for home-bound persons	mobile food carts
penal institutions	restaurants
schools	snack bars
temporary outdoor events	vending machines

Consider also the following characteristics that retail food establishments share.

1. The industry has a wide range of employee resources, from highly trained executive chefs to entry level front line employees. Employees may have a broad range of educational levels and communication skills. It may be difficult to conduct in-house training and to maintain a trained staff because employees may speak different languages or there may be high employee turnover.

2. Many establishments are start-up businesses operating without benefit of a large corporate support structure and having a relatively low profit margin and perhaps less capital to work with than other segments of the food industry.

3. There is an almost endless number of production techniques, products, menu items, and ingredients used. Suppliers, ingredients, menu items, or specifications may change frequently.

Using HACCP Principles at Retail to Manage and Enhance Food Safety

The goal in applying the HACCP principles at retail is to have MANAGERS AND OWNERS of establishments voluntarily take purposeful actions to ensure a safe outcome. Managing for food safety must be as fully integrated into your operations as those actions that you might take to open in the morning, ensure a profit and manage cash flow, oversee personnel, or any other aspect of your business. Only by putting in place an active, ongoing system, made up of actions intended to create the desired outcome, can you improve food safety. Application of the HACCP principles provides one system that can meet that criterion.

The HACCP principles, combined with a good set of Standard Operating Procedures (SOPs) and a sound training program, can be the most important part of a food safety management system. The HACCP plan that you are going to develop is YOUR PLAN. You may seek assistance from others such as your regulatory authority or an outside consultant, but the design, implementation, and success of the plan rests with you.

You will notice in various parts of this Guide, e.g., in Procedural Step 3, and in the Operational Steps: Preparation and Set Up and Packaging, that the Guide speaks inconclusively to the method of controlling personal hygiene and bare hand contact with ready-to-eat food. The distinction focuses on whether such hazards should be considered part of a prerequisite program and managed through SOPs or as critical control points.

The HACCP system is defined by seven principles.

1. **Perform a Hazard Analysis**. This first principle is about understanding your operation and determining what hazards are likely to occur. This usually involves defining the operational steps that you take as food enters and moves through your business. At this point, you will also try to understand how the people, equipment, methods, and foods all affect each other.

2. **Decide on the Critical Control Points (CCPs).** Which of the operational steps identified in principle #1 are critical to a safe outcome? Where can a hazard be prevented, eliminated, or reduced to an acceptable level? Which actions positively, absolutely, have to happen right? Is there a later step that will prevent, reduce, or eliminate the hazard? It is important to know that not all steps are CCPs. Generally, there are only a few CCPs in each process.

3. **Determine the Critical Limits**. Each CCP must have boundaries that define safety. How will you know when the CCPs are under control? What are the regulatory standards? What will you measure against? Critical limits are the measurements that define safety and can usually be found in the Food Code.

   For example, for cooking hamburgers, the Food Code sets the critical limits at 155 F for 15 seconds. When critical limits are not met, it could mean that the food is not safe.

4. **Establish Procedures to Monitor CCPs**. Once you have decided which operational steps are critical and have set the critical limits, someone needs to keep track of the CCPs in the flow of foods through your operation. Monitoring involves finding a way to see that the CCPs are kept under control and within the critical limits.

5. **Establish Corrective Actions**. What will you do when things go wrong? When monitoring your CCPs you will occasionally find an operational step that is outside of your critical limits. You need to plan ahead and decide what your actions will be, communicate those to your employees, and train them in those decisions. This preventive approach is at the heart of HACCP. Problems will arise. You need to find them and correct them before they can cause someone to become ill or injured.

6. **Establish Verification Procedures**. This principle is all about making sure that the whole system is in place and working. You will want to periodically make observations, calibrate equipment and temperature measuring devices, review records / actions, and discuss procedures with your employees. All of these activities will be for the purpose of ensuring that your system is real and checking to see if it needs to be modified or improved. Verification may also be conducted from the outside, such as by the regulatory authority or a third party.

7. **Establish a Record Keeping System**. There are certain written records or kinds of documentation that will be needed in order to verify that the system is working. Refer to the following table for examples of simplified "records." These records will normally involve the HACCP plan, itself, and your monitoring activities and serve to document that you really do have an on-going system in place. Record keeping should be as simple as possible in order to make it more likely that employees will have the time to keep them.

For more than 20 years industry and regulators have been exploring use of the HACCP principles in restaurants, grocery stores, and other retail food establishments. During that time, much has been learned about how these principles can be used in the varied operations, collectively referred to as retail food establishments. Most of this exploration has centered around the focal question of how to stay true to the definitions of HACCP and still make the principles useful to an industry that encompasses the broadest range of conditions.

Despite this diversity and range of conditions, those involved have discovered that the HACCP principles are useful tools for managing food safety. Over time, ways have been discovered to slightly modify the applications of HACCP to better fit retail food establishments. The following chart suggests some adaptations of applying the HACCP principles to retail food establishments.

HACCP Principle	Application Specific to Retail Level Food Establishments
Hazard Analysis	Analyze and organize by process rather than retail operations. Simplify by combining like operations into categories.
Define Critical Control Points	No change.
Establish Critical Limits	No change. Use of Food Code provisions.
Monitor	Simplify monitoring by standardizing procedures to a level of confidence that ensures safety, detects problems, and reduces the monitoring
Corrective Actions	No change.
Verification	No change.
Record Keeping	Simplify by using records already in existence, such as invoices, work schedules, and recipes.

Overview of the Process Approach

When conducting the hazard analysis, food manufacturers usually use food commodities as an organizational tool and follow the flow of one product. This is a very useful approach for producers or processors, since they are usually handling one product at a time. But at retail, foods of all types are worked together to produce the final product or menu item. This makes a different approach to the hazard analysis necessary. Conducting the hazard analysis by using the methods or processes common to a specific operation seems to work quite well. This is called the "Process Approach."

The process approach to the use of HACCP principles can best be described as dividing the many flows in an establishment into broad categories, analyzing the risks, and placing managerial controls on each grouping. The food that flows through retail food establishment operations can be placed into the three following processes:

Receive - Prepare - Serve
(other processes may occur, but there is NO cooking step)

Receive - Prepare - Cook - Hold - Serve
(other processes may occur, including thawing) .

Receive - Prepare - Cook - Cool - Reheat - Hot Hold - Serve
(other processes may occur, but the key is repeated trips through the temperature danger zone)

Your HACCP system must provide food safety controls for all hazards within each of these processes. Some operational steps, such as cooking, require procedures to control various hazards related to several different products. Therefore, a single operational step may have multiple control limits for multiple, product-specific hazards. For example, at the cooking step, poultry requires a final internal cooking temperature of 165 F for 15 seconds to control for Salmonellae. Ground beef, however, requires a final cooking temperature of 155 F for 15 seconds to control for E. coli 01 57:H7.

At the same time, some process steps, such as refrigerated storage, may encompass food safety procedures and critical limits that apply to all foods at that point in the flow of food.
Based on this understanding, you can blend a product-specific or menu-item HACCP approach into a process oriented approach. Controlling the hazard within each of these processes is equivalent to preparing a HACCP plan for each individual product, often a time and labor-intensive job.

Summary

HACCP is endorsed by the Food and Drug Administration. Combined with basic sanitation and a solid employee training program (prerequisite to the implementation of the HACCP principles), HACCP can provide the operator and employees a complete food safety management system.

The rest of this Guide will provide enough detail about how to organize your menu items so that you can voluntarily develop your own food safety system by applying the HACCP principles. It is important to remember that there are many resources that you can draw on during your efforts and some of these are listed at the end of this Guide. As mentioned in the Purpose and Scope portion of this Chapter, while setting up your food safety system using the HACCP principles, **you are encouraged to contact your regulatory authority for advice and assistance.**

The Process Approach

The Flow of Food

The flow of food, which is the path that food follows from receiving through serving, is important for determining where potentially significant food safety hazards may occur. At each operational step in the flow, active management of food preparation and processes is an essential part of business operations. With a HACCP system, you set up control measures to protect food at each stage in the process.

The illustrations of food processes listed below are not intended to be all inclusive. For instance, quick-service, full-service, and institutional providers are major types of food service operations. Each of these has its own individual food safety processes. These processes are likely to be different from a deli in a retail food store.

Some operations may have all three types of processes or variations of the three. Identifying the food process flows specific to your operation is an important part of providing a framework for developing a food safety management system.

Food Process With No Cook Step

RECEIVE--STORE--PREPARE--HOLD—SERVE

As mentioned in the Introduction, the important feature of this type of process is the absence of a cooking step. Heating foods destroys bacteria, parasites, and viruses, and is often a CCP. But since this particular food flow does not include cooking, there is no step that will eliminate or kill bacteria, parasites, or 'viruses. An example is tuna salad that is prepared and served cold. Control in this process will focus on preventing:

bacterial growth (e.g., storage under refrigeration)

contamination from employees (e.g., restriction of employees ill with diarrhea, proper handwashing, preventing bare hand contact with ready-to-eat foods, etc.)

cross-contamination from other foods (e.g., raw to ready-to-eat),
cross-contamination from soiled equipment (e.g., cleaning and sanitizing), and

obtaining foods from approved sources (e.g., a supplier of raw fish for sushi who adequately freezes fish to control parasites).

You should also think about some other factors.

- Are there any ingredients or menu items of special concern, such as those listed in Annex 2?
- Is this a potentially hazardous food requiring specific temperature controls?
- How will it be served? Immediately? On a buffet?
- Does this food have a history of being associated with illnesses?
- Will this require a great deal of preparation, making preparation time, employee health, and bare hand contact with ready-to-eat food a special concern?
- How will an employee ill with diarrhea be restricted from working with food?
- Are you serving food to a population that is known to be highly susceptible to foodborne illness (e.g., residents of health care facilities, persons in child or adult day care facilities, etc.)?

Food Preparation for Same Day Service

RECEIVE--STORE--PREPARE--COOK--HOLD—SERVE

In this process, a food is prepared and served the same day. The food will be cooked and held hot until service, such as chili. Generally, the food will pass through the temperature danger zone only once before it is served to the customer, thus minimizing the opportunity for bacterial growth.

The preparation step may involve several processes, including thawing a frozen food, mixing in other ingredients, or cutting or chopping. It is important to remember that added ingredients may introduce additional contaminants to the food. Cutting or chopping must be done carefully so that cross contamination from cutting boards, utensils, aprons, or hands does not occur. Control points at this operational step include good sanitation and handwashing.

During cooking, food will be subjected to hot temperatures that will kill most harmful bacteria, parasites, and viruses that might be introduced before cooking, making cooking a CCP. It is the operational step where raw animal foods are made safe to eat, and therefore, time and temperature measurement is very important. Temperature of foods during hot holding must be maintained until service so that harmful bacteria do not survive and grow.

Complex Processes

RECEIVE--STORE--PREPARE--COOK--COOL--REHEAT--HOT HOLD—SERVE

Failure to adequately control food product temperature is the one factor most commonly associated with foodborne illness. Foods prepared in large volumes or in advance for next day service usually follow an extended process flow. These foods are likely to pass through the temperature danger zone several times. The key in managing the operational steps within the process is to minimize the time foods are at unsafe temperatures.

In some cases, a variety of foods and ingredients that require extensive employee product preparation may be part of the process. A sound food safety management system will incorporate SOPs for personal hygiene and cross contamination prevention throughout the flow of the food.

Before you set up a management system for your operational steps, there are several factors you should consider. Multiple step processes require proper equipment and facilities. Your equipment needs to be designed to handle the volume of food you plan to prepare. For example, if you use a process that requires the cooling of hot food, you must provide equipment that will adequately and efficiently lower the food temperature as quickly as possible. If you find that a recipe is too hard to safely prepare, you may want to consider purchasing pre-prepared items from a reputable source.

Developing Your Food Safety System

Getting Started

Using a Team

Use of this Guide is most effective when a team approach is used for designing and implementing a plan based on the HACCP principles. A team could be comprised of the owner and the chef or cook. Although managers are responsible for designing the system, implementation involves the efforts and commitment of every employee. Education and training of both management and employees are important in their respective roles of producing safe foods. You may consider working with outside consultants, university extension services, and regulatory authorities to ensure your HACCP system is based on the best available science and will control identified hazards.

How to Use This Guide

This Guide contains a model for assessing significant food safety hazards at each operational step in the flow of food. A short introduction to each step highlights important food safety concerns. For each operational step there is a worksheet and a worksheet summary page which discuss the CCPs and critical limits. These critical food safety limits are included in the Food Code. In addition, Annex 3 of the Food Code provides the public health reasons behind each control measure.

This Guide addresses the significant food safety concerns for each operational step in the flow of food. For each step, a summary sheet and accompanying worksheet are provided to assist you in focusing on the controls that need to be in place in order to manage food safety hazards.

Procedural Step 1: Group Menu Items

To get started, review how your menu items flow through your operation, note whether they undergo a cook step for same day serving, receive additional cooling and reheating following a cook step, or have no cook step involved. Refer to Chapter 2 for organizing your menu items by Process 1, 2, and 3.

Looking at your menu, place each menu item or similar menu items (like "hot soups" or of cold salads") into the appropriate group. You may discover that more than one food process is conducted within your operation. You will also need to consult the Annexes to identify menu items that need very careful and special attention throughout the use of this Guide. These menu items may pose special hazards that are not always readily apparent. If your operation serves any of the menu items listed in the Annexes, consult with your regulatory authority for additional information. To accomplish the first procedural step in developing your food safety management system, identify the food processes specific to your menu items.

Chart 1: Process-Specific Lists

List your menu items that belong to one of the three processes.

Process #1	Process #2	Process #3
List menu foods: Examples: salad greens fish for sushi fresh vegetables oysters or clams served raw tuna salad Caesar salad dressing coleslaw sliced sandwich meats sliced cheese	List menu foods: Examples: hamburgers soup du jour hot vegetables entrees for "special of the day" cooked eggs	List menu foods: Examples: soups gravies sauces large roasts chili taco filling egg rolls

Process number 1: Food preparation with no cook step - ready-to-eat food that is stored, prepared, and served.

Process number 2: Food preparation for same day service - food that is stored, prepared, cooked, and served.

Process number 3: Complex food preparation - food that is stored, prepared, cooked, cooled, reheated, hot held, and served.

Procedural Step 2: Conduct Hazard Analysis

In developing a food safety system, you need to identify the hazards that exist in the flow of foods in your operation from receiving to serving. Hazards include:

- pathogens or toxins present in food when you receive them
- pathogens that may be introduced during preparation (example: using a raw animal food as one ingredient)
- pathogen growth or toxin production during storage, preparation, or holding
- pathogens or toxins that survive heating, and
- contaminants (i.e., pathogens, chemicals, physical objects), that are introduced to food by food workers or equipment.

Since you have grouped your menu items, including ingredients, into the three processes on Chart 1, you can identify hazards that are associated with each process. You will see that the more complex the process is, the greater are the opportunities for hazards to occur.

In consultation with your regulatory authority, you need to identify the hazards associated with various foods and ingredients, such as:

- Salmonella and Campylobacter jejuni in raw poultry,
- E. coli 0157: H7 in raw ground beef, Staphylococcus aureus toxin formation in cooked ham
- Bacillus cereus spore survival and toxin formation in cooked rice
- Clostridium perfringens spore survival and subsequent growth in cooked foods, and
- Hazards specific to seafood, (see Annex 1).

This list is only a brief sample of hazards associated with specific foods. By identifying the hazards, you will be able to determine CCPs and critical limits on the worksheet. Another way of fulfilling the hazard analysis step is to understand the hazards associated with your specific menu items (Annex 3 of the Food Code is a resource for this purpose) and to adhere to the critical limits established in the Food Code. Those critical limits are based on the anticipated hazards.

Food Safety Management Worksheets and Summaries for Operational Steps

Worksheets and summaries are provided to enable you to:

- Identify those operational steps in the food flow that are specific to your operation
- Write in your SOPs which are the general procedures that cross all flows and products (refer to Chapter 4, Prerequisite Programs, for further discussion)
- Reference the CCPs and critical limits pertaining to those process steps
- Develop monitoring procedures and corrective actions which are customized to fit your operation
- Consider the type of record keeping you need to document you are controlling significant food safety hazards.

HACCP allows the flexibility for you to customize a food safety management system specific to your operations. The worksheets are provided to assist you in developing procedures to:

- Monitor CCPs
- Take corrective actions when critical limits are not met
- Establish a verification procedure
- Establish a record keeping system.

Review the following worksheets and the summary page for each operational step. Determine the ones that are applicable to your operation and make copies of them so you can fill in your groupings of menu items (which you did preliminarily in Procedural Step 1). Then continue to use the forms and complete the information as you work through Procedural Steps 3 through 9.

Operational Step 1: Receiving

At receiving, your main concern is contamination from pathogens and the formation of harmful toxins. Obtaining food from approved sources and at proper temperatures are important purchase specifications for preventing growth and contamination during receiving. Approved sources are suppliers who are regulated and inspected by appropriate regulatory authorities.

Ready-to-eat, potentially hazardous food is a special concern at receiving. Because this food will not be cooked before service, microbial growth could be considered a significant hazard for receiving refrigerated, ready-to-eat-foods. Having SOPs in place to control product temperature is generally adequate to control the hazards present at receiving of these products. Besides checking the product temperature, you will want to check the appearance, odor, color, and condition of the packaging.

Federal regulations require that processors of **seafood and seafood products** for interstate distribution have a HACCP plan. These establishments are approved sources for seafood, and you may ask your interstate seafood supplier for documentation that the firm has a HACCP plan in place. Processors of seafood and seafood products that are sold or distributed only within a state may or may not be required to have a HACCP plan, depending on the state, local, or tribal regulations.

Special consideration should be given to certain species of **finfish** and **raw molluscan shellfish**. Molluscan shellfish (oysters, clams, mussels, and scallops) that are received raw in the shell or shucked must be purchased from suppliers who are listed on the FDA Interstate Certified Shellfish Shippers' List or on a list maintained by your state shellfish control authority. Shellfish received in the shell must bear a tag (or a label for shucked shellfish) which states the date and location of harvest, in addition to other specific information.

Finfish harvested from certain areas may naturally contain a certain toxin that is not readily apparent. This toxin is called ciguatera. Other finfish may develop toxins after harvest if strict temperature control is not maintained. This toxin is called scombrotoxin. Temperature control is important at receiving because this toxin can not be eliminated by cooking. For more information on toxins in reef finfish, histamine formation in certain species, and parasites in raw finfish requiring control, refer to Annex 1.

Operational Step 1: Receiving

PROCESS	MENU ITEM	HAZARD	CCP	CRITICAL LIMITS	MONITORING	CORRECTIVE ACTIONS	VERIFICATION	RECORDS
Process #1	Examples: Salads Sushi	* Microbial contamination * Bacterial growth * Parasites * Scombrotoxin * Ciguatera or other toxin contamination * Chemical contamination	yes _____ or no _____	Receive at 41^{O}F or below Approved source Seafood HACCP plan Proper chemical storage/use				
Process #2	Examples: Hamburgers Mahi-mahi	* Microbial contamination * Bacterial growth * Scombrotoxin * Ciguatera or other toxin contamination * Chemical contamination	yes _____ or no _____	Receive at 41^{O}F or below Approved source Seafood HACCP plan Proper chemical storage/use				
Process #3	Example: Soups	* Microbial contamination * Bacterial growth * Scombrotoxin * Ciguatera or other toxin contamination * Chemical contamination	yes _____ or no _____	Receive at 41^{O}F or below Approved source Seafood HACCP plan Proper chemical storage/use				
SOPs								

Process number one: Food preparation with no cook step - ready- to-eat food that is stored, prepared, and served.
Process number two: Food preparation for same day service - food that is stored, prepared, cooked, and served.
Process number three: Complex food preparation - food that is stored, prepared, cooked, cooled, reheated, hot held, and served.

Operational Step 2: Storage

When food is in refrigerated storage, your management system should focus on **preventing the growth** of bacteria that may be present in the product. This is primarily achieved through temperature control. Special attention needs to be given to controlling and monitoring the temperatures of potentially hazardous ready-to-eat foods.

When determining the **monitoring frequency** of product storage temperature, it is important to make sure that the interval between temperature checks is established to ensure that the hazard is being controlled and time is allowed for an appropriate corrective action. For example, If you are storing potentially hazardous ready-to-eat foods under refrigeration, you may decide to set a critical limit for the refrigeration units to operate at 41 OF or below. You may also want to set a target, or operating limit, of 40 F for example, in order to provide a safety cushion that allows you the opportunity to see a trend toward exceeding 41 F and to intervene with appropriate corrective actions.

Monitoring procedures for ready-to-eat food ideally include internal product temperature checks. You need to assess whether it is realistic and practical for you to do this, depending, on the volume of food you are storing.

You may choose to base your monitoring system on the air temperature of the refrigerated equipment as an SOP. How often you need to monitor the air temperature depends on:

- Whether the air temperature of the refrigerator accurately reflects the internal product temperature - (remember, your food safety refrigeration temperature must be based on the internal product temperature of the food stored within a refrigeration unit, not the air temperature)
- The capacity and use of your refrigeration equipment
- The volume and type of food products stored in your cold storage units
- The SOPs that support monitoring this process, and shift changes and other operational considerations.

Standard operating procedures can be developed to control some hazards and assist in implementing a food safety system that minimizes the potential for **bacterial growth** and **contamination**. The **control of cross contamination** can be done by separating raw foods from ready-to-eat products within your operation's refrigeration and storage facilities.

Special consideration should be given to the storage of scombroid fish due to the potential formation of histamine, a chemical hazard. To control histamine formation in scombroid toxin-forming fish, it is recommended that storage be a CCP with the critical limit not to exceed 41 OF, as stated in the Food Code, unless you can show through scientific data that the food safety hazard will not result.

Operational Step 2: Storage

PROCESS	MENU ITEM	HAZARD	CCP	CRITICAL LIMITS	MONITORING	CORRECTIVE ACTIONS	VERIFICATION	RECORDS
Process #1	Examples: Salads Sushi Salads Sushi	* Bacterial growth * Cross contamination * Parasites * Chemical contamination contamination	yes _____ or no _____	Store at 41^{O}F or Below Separate raw from ready-to-eat food Freeze fish to be consumed raw @ -4 for 7 days or -31^{O} F for 15 hours Proper chemical storage/use				
Process #2	Examples: Hamburgers Mahi-mahi	* Bacterial growth * Scombrotoxin * Cross contamination * Chemical contamination	yes _____ or no _____	Store at 41^{O}F or Below Separate raw from ready-to-eat food Proper chemical storage/use				
Process #3	Example: Soups	* Bacterial growth * Scombrotoxin * Cross contamination * Chemical contamination	yes _____ or no _____	Store at 41OF or Below Separate raw from ready-to-eat food Proper chemical storage/use				
SOPs								

Process number one: Food preparation with no cook step - ready-to-eat food that is stored, prepared, and served.
Process number two: Food preparation for same day service - food that is stored, prepared, cooked , and served.
Process number three: Complex food preparation - food that is stored, prepared, cooked, cooled, reheated, hot held, and served.

Operational Step 3: Preparation

Of all the operational steps in food processes, preparation has the greatest variety of activities that must be controlled, monitored, and in some cases documented. It is impossible to include in this model a summary guide that covers the diversity in menus, employee skills, and facility design that impact the preparation of food. The preparation step may involve several processes, including thawing a frozen food, mixing together several ingredients, cutting, chopping, slicing, or breading.

At the preparation step, SOPs can be developed to control some hazards and assist in implementation of a food safety system that minimizes the potential for **bacterial 'growth** and **contamination** from employees and equipment.

Front-line employees will most likely have the greatest need to work with the food. A well designed **personal hygiene program** that has been communicated to all employees will minimize the potential for bacterial, parasitic, and viral contamination. Your program must include instructions to your employees as to when and **how to wash their hands**. Procedures need to be in place that either **eliminate employees' hand contact with ready-to-eat foods**, or implement an alternative personal hygiene program that provides an equivalent level of control of bacterial, parasitic, and viral hazards. It is also very important to identify and **restrict ill employees** from working with food, especially if they have **diarrhea**.

Procedures must be in place to **prevent cross contamination** from utensils and equipment. Designated areas or procedures that separate the preparation of raw foods from ready-to-eat foods minimize the potential for bacterial contamination. **Proper cleaning and sanitizing** of equipment and work surfaces are an integral SOP to this operational step.

Batch preparation is an important tool for controlling bacterial growth because limiting the amount of food prepared **minimizes the time** the food is kept at a temperature that allows growth. Planning your preparation ahead assists in minimizing the time food must be out of temperature at this operational step. Batch preparation also breaks the growth cycle of bacteria before they can reach dangerous levels.

When **thawing frozen foods**, maintaining proper product temperature and managing time are the primary controls for minimizing bacterial growth. Procedures need to be in place to minimize the potential for microbial, chemical, and physical contamination during thawing.

Use of **prechilled ingredients** to prepare a cold product, such as tuna salad, will assist you in maintaining temperature control for this process.

Special consideration should be given to disallowing bare hand contact in the preparation of ready-to-eat foods. You need to control the introduction of hazards during preparation. How will you accomplish controlling the hazard presented by hand contact with ready-to-eat food? You should review your operation to determine whether this operational step will be controlled as a CCP or an SOP.

Operational Step 3: Preparation

PROCESS	MENU ITEM	HAZARD	CCP	CRITICAL LIMITS	MONITORING	CORRECTIVE ACTIONS	VERIFICATION	RECORDS
Process #1	Example: Salads	* Bacterial growth * Cross contamination * Contamination from employees * Chemical contamination contamination	yes _____ or no _____	Store at 41^{O} F or below or use time to control growth Separate raw from ready-to-eat food Restrict ill employees Restrict hand contact Proper chemical storage/use				
Process #2	Examples: Hamburgers Mahi-mahi	* Bacterial growth * Cross contamination * Contamination from employees * Chemical contamination	yes _____ or no _____	Store at 41^{O} F or below or use time to control growth Separate raw from Ready-to-eat food Restrict ill employees Control bare hand contact Proper chemical storage/use				
Process #3	Example: Soups	* Bacterial growth * Cross contamination * Contamination from employees * Chemical contamination	yes _____ or no _____	Store at 41^{O}F or below or use time to control growth Separate raw from ready-to-eat food Restrict ill employees; Control bare hand contact Proper chemical storage/use				
SOPs								

Process number one: Food preparation with no cook step - ready-to-eat food that is stored, prepared, and served.
Process number two: Food preparation for same day service - food that is stored, prepared, cooked , and served.
Process number three: Complex food preparation - food that is stored, prepared, cooked, cooled, reheated, hot held, and served.

Operational Step 4: Cooking

This operational step only applies to those foods that you have listed in Processes #2 and #3. **Cooking foods of animal origin is the most effective operational step in food processes for reducing and eliminating biological contamination**. Hot temperatures will kill most harmful bacteria and with relatively few exceptions, such as cooking plant foods, this is a CCP. It is at this step that food will be made safe to eat. Therefore, product temperature and time measurements are very important. If the appropriate product temperature for the required amount of time is not achieved, bacteria, parasites, or viruses may survive in the food.

Critical time and temperature limits vary according to the type of food. Employees should view ensuring proper cooking temperatures as an essential element in producing an acceptable product. A final cooking time and temperature chart for specific foods is included for your review. Simply reference the foods specific to your food establishment and incorporate the appropriate critical time and temperature limits into your management system.

You will need to determine the best system for you to use that will ensure that the proper cooking temperature and time are reached. Checking the internal product temperature is the most desirable monitoring method. However, when large volumes of food are cooked, a temperature check of each individual item may not be practical. For instance, a quick service food service operation may cook several hundred hamburgers during lunch. If checking the temperature of each hamburger is not reasonable for you to do, then you need to routinely verify that the specific process and cooking equipment are capable of attaining a final internal product temperature at all locations in or on the cooking equipment.

Once a specific process has been shown to work for you, the frequency of record keeping may be reduced. In these instances, a record keeping system should be established to provide scheduled product temperature checks to ensure that the process is working.

Special consideration should be given to time and temperature in the cooking of fish and other raw animal foods. **To control the pathogens, it is recommended that cooking be a CCP, based upon the critical limits established by the Food Code**, unless you can show through scientific data that the food safety hazard will not result.

Operational Step 4: Cooking

PROCESS	MENU ITEM	HAZARD	CCP	CRITICAL LIMITS	MONITORING	CORRECTIVE ACTIONS	VERIFICATION	RECORDS
Process #1	Example: Salads Sushi	Does not apply	Does not apply	Does not apply	Does not apply	Does not apply	Does not apply	Does not apply
Process #2	Examples: Hamburgers Mahi-Mahi	Bacterial, parasitic, or viral survival or growth	yes _____ or no _____	Cook to Product Internal Temperature – Time See Chart 2				
Process #3	Example: Soups	Bacterial, parasitic, or viral survival or growth	yes _____ or no _____	Same as Process #2				
SOPs								

Process number one: Food preparation with no cook step - ready-to-eat food that is stored, prepared, and served.
Process number two: Food preparation for same day service - food that is stored, prepared, cooked , and served.
Process number three: Complex food preparation - food that is stored, prepared, cooked, cooled, reheated, hot held, and served.

CHART 2: FOOD CODE COOKING TEMPERATURES AND TIMES

Product	Final Internal Temperature	Time
1a. Poultry Wild Game Animals Stuffed Fish Stuffed Meat Stuffed Pasta Stuffed Poultry Stuffed Ratites or Stuffing containing Fish Meat Poultry or Ratites	1a. 165^{O}F	1a. 15 seconds
1b. Animal foods cooked in a microwave oven	1b. 165^{O}F; food rotated, stirred, covered	1b. Cover and allow to stand for 2 minutes
2a. Pork, ratites, or injected meats	2a. 155^{O}F	2a. 15 seconds
2b. Ground meat, fish, or game animals commercially raised for food	2b. 155^{O}F	2b. 15 seconds
2c. Game Animals under a voluntary inspection program	2c. 155^{O}F	2c. 15 seconds
2d. Raw shell eggs that are NOT prepared for immediate service	2d. 155^{O}F	2d. 15 seconds

CHART2: FOOD CODE COOKING TEMPERATURES AND TIMES

Product	Final Internal Temperature	Time
3a. Raw shell eggs broken and prepared in response to consumer order and for immediate service	3a. 145^{O}F	3a. 15 seconds
3b. Fish and Meat including Game Animals except as specifically referenced on this chart	3b. 145^{O}F	3b. 15 seconds
4a. Fruit and vegetables cooked for hot holding	4a. 140^{O}F or above	4a. Instantaneous
4b. Ready-to-eat food from a commercially sealed container for hot holding	4b. 140^{O}F or above	4b. Instantaneous
4c. Ready-to-eat food from an intact package (from a food Processing plant inspected by the regulatory authority with Jurisdiction over the plant) for hot holding	4c. 140^{O}F or above	4c. Instantaneous
5a. Beef Roast Comed Beef Roasts *Preheated Oven Temperatures*	5a. <u>LESS THAN 10 lbs</u>. Still Dry: 350^{O}F or more Convection: 325^{O}F or more High Humidity: 250^{O}F to 130 F <u>MORE THAN 10 lbs</u> Still dry: 250^{O}F or more Convection: 250^{O}F or more High Humidity: 250^{O}F or less	
5b. Beef Roast/Corned Beef Roasts *Internal Food Temperature for Specified Amount of Time*	5b. <u>ACHIEVE ONE OF THE FOLLOWING</u>: 130^{O}F for 121 Minutes 132^{O}F for 77 Minutes 134^{O}F for 47 Minutes 136^{O}F for 32 Minutes 138^{O}F for 19 Minutes 140^{O}F for 12 Minutes 142^{O}F for 8 Minutes 144^{O}F.for 5 Minutes 145^{O}F for 3 Minutes	

Operational Step 5: Cooling

This operational step is only used for those foods that you have listed in Process #3. One of the most labor intensive operational steps is **rapidly cooling** hot foods to control microbial growth. Excessive time for the cooling of potentially hazardous foods has been consistently identified as one of the factors contributing to foodborne illness. Foods that have been cooked and held at improper temperatures provide an excellent environment for the growth of disease causing microorganisms that may have survived the cooking process (spore-formers). Recontamination of a cooked food item by poor employee practices or cross contamination from other food products, utensils and equipment is a concern at this operational step.

Special consideration should be given to **large food items**, such as roasts, turkeys, thick soups, stews, chili, and large containers of rice or refried beans. These foods take a long time to cool because of their mass and volume. If the hot food container is tightly covered, the cooling rate will be further slowed down. By **reducing the volume** of the food in an individual container and **leaving an opening for heat to escape** by keeping the cover loose, the rate of cooling is dramatically increased.

Commercial refrigeration equipment is designed to hold cold food temperatures, not cool large masses of food. Some **alternatives for cooling** foods include:

- Using **rapid chill** refrigeration equipment designed to cool the food to acceptable temperatures quickly by using increased compressor capacity and high rates of air circulation;

- Avoiding the need to cool large masses by **preparing smaller batches** closer to periods of service;

- Stirring hot food while the food container is within an **ice water bath**; or

- **Redesigning your recipe** so that you prepare and cook a smaller or concentrated base and then add enough cold water or ice to make up the volume that you need. This may work for some water-based soups, for example.

Whatever the cooling method you choose, you need to verify that the process works. Once again if a specific process has been shown to work for you, the frequency of record keeping may be reduced. A record keeping system should be established to provide scheduled product temperatures checks to ensure the process is working.

Operational Step 5: Cooling

PROCESS	MENU ITEM	HAZARD	CCP	CRITICAL LIMITS	MONITORING	CORRECTIVE ACTIONS	VERIFICATION	RECORDS
Process #1	Examples: Salads Sushi	Does not apply	Does not apply	Does not apply	Does not apply	Does not apply	Does not apply	Does not apply
Process #2	Examples: Hamburgers Mahi-mahi	Does not apply	Does not apply	Does not apply	Does not apply	Does not apply	Does not apply	Does not apply
Process #3	Example: Soups	* Bacterial growth * Cross contamination * Contamination from employees or equipment	yes _____ or no _____	Cool food from 140^{O}F to 70^{O}F within 2 hours and from 70^{O}F to 41^{O}F within 4 hours Separate raw from ready-to-eat food Restrict ill employees; control bare hand contact				
SOPs								

Process number one: Food preparation with no cook step - ready to eat food that is stored, prepared, and served.
Process number two: Food preparation for same day service -food that is stored, prepared, cooked, and served.
Process number three: Complex food preparation - food that is stored, prepared, cooked, cooled, reheated, hot held, and served.

Operational Step 6: Reheating

This operational step applies only to those foods that you listed in Process #3. If food is held at improper temperatures for enough time, pathogens have the opportunity to multiply to dangerous numbers. Proper reheating provides an important control for eliminating these organisms. It is especially effective **in reducing contamination from bacterial spore-formers which survived the cooking process** and may have multiplied because foods were held at improper temperatures.
Although proper reheating will kill most organisms of concern, it will not eliminate toxins, such as that produced by Staphylococcus aureus. If microbial controls and SOPs at previous operational steps have not been followed correctly and Staph toxin has been formed in the food, reheating will not make the food safe.

Incorporating a comprehensive personal hygiene program throughout the process will minimize the risk from Staph toxin. Along with personal hygiene, preventing cross contamination through the use of cleaned and sanitized equipment and utensils is an important control measure.

Special consideration should be given to the time and temperature in the reheating of cooked foods. **To control the pathogens, it is recommended that reheating be a CCP, based upon the critical limits established by the Food Code**, unless you can show through scientific data that the food safety hazard will not result.

Operational Step 7: Holding

All three processes may involve holding. Proper temperature of the food while being held is essential in controlling the growth of harmful bacteria. Cold temperature holding may occur in Processes 1, 2, or 3. Hot temperature holding occurs primarily only in Processes 2 and 3. Where there is a cooking step as a CCP to eliminate pathogens, all but the spore-forming organisms should be killed or inactivated**. If cooked food is not held at the proper temperature, the rapid growth of these spore-forming bacteria is a major food safety concern**.

When food is held, cooled, and reheated in a food establishment there is an increased risk from contamination caused by personnel, equipment, procedures, or other factors. Harmful bacteria that are introduced into a product that is not held at proper temperature have the opportunity to multiply to large numbers in a short period of time. Once again management of personal hygiene and the prevention of cross contamination impact the safety of the food at this operational step.

Keeping food products at 140OF or above during hot holding and keeping food products at or below 41 OF is effective in preventing microbial growth. As an alternative to temperature control, the Food Code details actions when time alone is used as a control, including a comprehensive monitoring and food marking system to ensure food safety.

How often you monitor the temperature of foods during hot holding determines what type of corrective action you are able to take when 140OF is not met. If the critical limit is not met, your options for corrective action may include evaluating the time the food is out of temperature to determine the severity of the hazard and based on that information, reheating the food, if appropriate, or discarding it. Monitoring frequency may mean the difference between reheating the food to 1650F or discarding it.

When determining the **monitoring frequency** of cold product temperatures, it is important to make sure that the interval between temperature checks is established to ensure that the hazard is being controlled and time is allowed for an appropriate corrective action. For example, If you are holding potentially hazardous ready-to-eat foods under refrigeration, such as potato salad at a salad bar, you may decide to set a critical limit at 41' F or below. You may also want to set a target, or operating limit, of 400 F for example, in order to provide a safety cushion that allows you the opportunity to see a trend toward exceeding 41 OF and to intervene with appropriate corrective actions.

Special consideration should be given to the time and temperature in the hot or cold holding of potentially hazardous foods to control pathogens. It is recommended that hot or cold holding be a CCP, based upon the critical limits established by the Food Code, unless you can show through scientific data that the food safety hazard will not result.

Operational Step 7: Holding

PROCESS	MENU ITEM	HAZARD	CCP	CRITICAL LIMITS	MONITORING	CORRECTIVE ACTIONS	VERIFICATION	RECORDS
Process #1	Examples: Salads Sushi	* Bacterial, parasitic, or viral introduction, survival, growth	yes _____ or no _____	41^{O}F				
Process #2	Examples: Hamburgers Mahi-mahi	* Bacterial, parasitic, or viral introduction, survival, growth	yes _____ or no _____	140^{O}F or 41^{O}F				
Process #3	Example: Soups	* Bacterial, parasitic, or viral introduction, survival, growth	yes _____ or no _____	140^{O}F or 41^{O}F				
SOPs								

Process number one: Food preparation with no cook step - ready-to-eat food that is stored, prepared, and served.
Process number two: Food preparation for same day service - food that is stored, prepared, cooked, and served.
Process number three: Complex food preparation - food that is stored, prepared, cooked, cooled, reheated, hot held, and served.

Operational Step 8: Set Up and Packing

Set up and packing is an operational, step used by some retail food establishments ,including caterers (e.g., restaurant/caterer or interstate conveyance caterer), commissaries, grocery stores (for display cases), schools, nursing homes, hospitals, or services such as delivery of meals to home-bound persons. Set up and packing can be controlled through an SOP and may involve wrapping food items, assembling these items onto trays, and packing them into a transportation carrier or placing them in a display case. An example would be an airline flight kitchen where food entrees are wrapped, assembled, and placed into portable food carts which are taken to a final holding cooler. Hospital kitchens would be another example where patient trays are assembled and placed into carriers for transportation to nursing stations. Food may be placed into bulk containers for transportation to another site where it is served.

This operational step might not be considered a CCP, but it is a special consideration when setting up your program. This process can be controlled by strict adherence to SOPs to minimize the potential for bacterial contamination and growth, to eliminate bare hand contact with ready-to-eat foods, to ensure proper handwashing, and to ensure food comes into contact with cleaned and sanitized surfaces.

Following final assembly into either individual trays or into bulk containers, the food may be held for immediate service or for transportation to another site for service. This hot holding or cold holding operational step needs to be evaluated in the same manner as other holding operational steps on the worksheet. Temperature control or using time as a control measure during transportation, and holding and serving at a remote site must be evaluated and managed as part of your food safety system.

Special consideration should be given to **time - temperature** controls and the prevention **of cross contamination** from equipment and utensils and **contamination from employees' hands**. This process may be adequately controlled through an SOP; however, holding and transportation should be considered CCPs.

Operational Step 8: SET UP AND PACKING

PROCESS	MENU ITEM	HAZARD	CCP	CRITICAL LIMITS	MONITORING	CORRECTIVE ACTIONS	VERIFICATION	RECORDS
Process #1	Examples: Salads Sushi	* Bacterial Growth * Microbial contamination from employees	yes _____ or no _____	41^{O}F No bare hand contact or equivalent alternative				
Process #2	Examples: Hamburgers Mahi-mahi	* Bacterial Growth * Microbial contamination from employees	yes _____ or no _____	140^{O}F or 41^{O}F No bare hand contact or equivalent alternative				
Process #3	Example: Soups	* Bacterial Growth * Microbial contamination from employees	yes _____ or no _____	140^{O}F or 41^{O}F No bare hand contact or equivalent alternative				
SOPs								

Process number one: Food preparation with no cook step - ready-to-eat food that is stored, prepared, and served.
Process number two: Food preparation for same day service - food that is stored, prepared, cooked, and served.
Process number three: Complex food preparation - food that is stored, prepared, cooked, cooled, reheated, hot held, and served.

Operational Step 9: Serving

This is the final operational step before the food reaches the customer. When employees work with food and food contact surfaces, they can easily spread bacteria, parasites, and viruses and contaminate these items. **Managing employees' personal hygienic practices is important to controlling these hazards.** A management program for employee personal hygiene includes proper handwashing, the appropriate use of gloves and dispensing utensils, and controlling bare hand contact with ready-to eat foods.

Minimizing the growth of bacteria is also a concern at hot and cold holding customer display areas. Maintaining food products at proper temperature within these display units will control the growth of microorganisms. Refer to the HOLDING worksheet for additional information.

Special consideration needs to be given to minimizing contamination from the customer. Customer self-service displays, such as salad bars, require specific procedures to protect the food from contamination. Some suggestions for protecting food on display include:

- The use of packaging,
- Counter, service line, or salad bar food guards,
- Display cases,
- Suitable utensils or effective dispensing methods,
- Not mixing an old product with fresh, and
- Having employees monitor self-serve stations.

Preventing **cross contamination** from soiled utensils and equipment will minimize the potential for bacterial contamination of ready-to-eat foods.

Operational Step 9: Serving

PROCESS	MENU ITEM	HAZARD	CCP	CRITICAL LIMITS	MONITORING	CORRECTIVE ACTIONS	VERIFICATION	RECORDS
Process #1	Example: Salads Sushi	* Bacterial, parasitic, viral or physical contamination	yes _____ or no _____					
Process #2	Examples: Hamburgers Mahi-mahi	* Bacterial, parasitic, viral or physical contamination	yes _____ or no _____					
Process #3	Example: Soups	* Bacterial, parasitic, viral or physical contamination	yes _____ or no _____					
SOPs								

Process number one: Food preparation with no cook step - ready-to-eat food that is stored, prepared, and served.
Process number two: Food preparation for same day service - food that is stored, prepared, cooked , and served.
Process number three: Complex food preparation - food that is stored, prepared, cooked, cooled, reheated, hot held, and served.

Procedural Step 3: Identify CCPs and Critical Limits

The CCPs column identifies places in the flow of food where you can have a significant impact in controlling food safety hazards. A measurable critical limit has been identified for each of these CCPs. These critical limits provide the baseline for measuring the effectiveness of your food safety procedures.

For each of your operational steps, within your operation, review the CCPs and critical limits needed to minimize or eliminate significant food safety hazards. Does your operation currently have control measures in place that are at least equivalent to these critical limits?

On the worksheet, you will need to decide whether the operational step is a CCP or whether the hazard is controlled by your SOPs that address the prerequisite program elements discussed in Chapter 4.

In some operational step worksheets, such as the Cooking step, the Guide recommends that the step be considered a CCP, because there is no practical alternative to ensure control of the hazard. In other operational steps, you may have a choice as to how you will control the hazard. For example, in the preparation step for ready-to-eat foods, you will identify contamination from employees' hands as a hazard. When controlling that hazard as a CCP, you must also identify the critical limits, establish monitoring and corrective actions, verification procedures, and records. Alternatively, you may choose to control that hazard by instituting an SOP that disallows bare hand contact with ready-to-eat food. You will need to decide the most effective method of controlling the hazard, i.e., as a CCP or through use of an SOP.

Procedural Step 4: Monitor Critical Control Points

Use the worksheet to develop procedures, customized to your operation, for monitoring your CCPs. Consideration should be given to determining answers to the following questions.

- What critical limit at the CCP are you measuring?
- How is it monitored?
- When and how often will the CCP be monitored?
- Who will be responsible for monitoring it?

Monitoring is observing or measuring specific operational steps in the food process to determine if your critical limits are being met. This activity is essential in making sure your critical food processes are under control. It will identify where a loss of control occurs or if there is a trend toward a loss of control of a critical food process. Needed adjustments will then become obvious.

In your food safety management system, certain processes have been identified as CCPs. **What you are going to monitor** depends on the critical limits you have established at each CCP. Minimum critical limits for many CCPs have been established by the Food Code. For example, cooking hamburger (which is the CCP) to 155' F for 15 seconds (which is the critical limit) will kill most harmful bacteria. Therefore, final temperature and time measurements are very important and you need to determine how you will effectively monitor the critical limits for each CCP.

Is monitoring equipment needed to measure a critical limit? The equipment you choose for monitoring must be accurate and routinely calibrated to ensure critical limits are met. For example, a thermocouple with a thin probe might be the most appropriate tool for measuring the final product temperature of hamburger patties.

When deciding how often you need to monitor, make sure that the monitoring interval will be reliable enough to ensure the hazard is being controlled. Your procedure for monitoring should be simple and easy to follow.

Individuals chosen to be responsible for a monitoring activity may be a manager, line-supervisor, or a designated employee. Your monitoring system will only be effective if employees are given the knowledge, skills, and responsibility for serving safe food. Train your employees to carefully follow your procedures, monitor CCPs, and take corrective action if critical limits are not met.

Procedural Step 5: Develop Corrective Actions

Decide what type of corrective action you need to take if a critical limit is not met.

- What measures do you expect employees to take to correct the problem?
- Is the corrective action understood by your employees?
- Can the corrective action be easily implemented?
- Are different options needed for the appropriate corrective actions, depending on the process and monitoring frequency?
- How will these corrective actions be documented and communicated to management so the system can be modified to prevent the problem from occurring again?

Whenever a critical limit is not met, **a corrective action must be carried out immediately**. Corrective actions may be simply continuing to heat food to the required temperature. Other corrective actions may be more complicated, such as rejecting a shipment of raw oysters that does not have the required tags or segregating and holding a product until an evaluation is done.

In the event that a corrective action is taken, you should reassess and modify if necessary your food safety system based upon the HACCP principles. Despite the best system, errors occur during food storage and preparation. A food safety system based upon the HACCP principles is designed to detect errors and correct them before a food safety hazard occurs. It is a benefit to industry and regulators to be able to show that immediate action is taken to ensure that no food product that may be injurious to health is served to or purchased by a customer. It is important to document all corrective actions in written records.

Procedural Step 6: Conduct On-Going Verification

Description

Because HACCP is a system to maintain **continuous control** of food safety practices, implementation of the plan needs to be audited or verified. Verification is usually performed by someone other than the person who is responsible for performing the activities specified in the plan. That person might be a manager, supervisor, designated person, or the regulatory authority.

There is **on-going verification**, which is conducted frequently, such as daily, weekly, monthly, etc., by designated employees of the establishment. It is important to note that routine monitoring should not be confused with audit or verification methods or procedures.

There is long-term verification, which is done less frequently. This will be discussed in Procedural Step 8.

Verification is an oversight auditing process to ensure that the HACCP plan and SOPs continue to:

- be adequate to control the hazards identified as likely to occur, and
- be consistently followed (i.e., a comparison is made regarding observed, actual practices and procedures with what is written in the plan).

On-going Verification activities include:

- observing the person doing the monitoring: is monitoring being done as planned?
- reviewing the monitoring records:

  are records completed accurately?

  do records show that the predetermined frequency of the monitoring is followed?
- was the planned corrective action taken when the person monitoring found and recorded that the critical limit was not met?
- do records of the calibration of monitoring equipment indicate that the equipment was operating properly?

Verification Procedures

Procedures may include the following activities:

- observe the person conducting the activities at the CCPs and recording information,
- check monitoring records
- check corrective action records
- periodically review the total plan
- test product in process or finished product
- review equipment calibration records, and
- review recording thermometer accuracy (large operations and some processes such as large quantity cook and chill operations or smokers, etc.)

Verification Frequency

Verification should occur at a frequency that can ensure the HACCP plan is being followed **continuously** to:

- avoid adulterated/unsafe product getting to the consumer,
- be able to take corrective action without loss of product,
- ensure prescribed personnel practices are consistently followed,
- ensure personnel have the tools for proper personal hygiene and sanitary practices (e.g., handwashing facilities, sanitizing equipment, cleaning supplies, temperature measuring devices, and sufficient gloves, etc.),
- follow/comply with the control procedures established, and
- conduct calibrations as needed depending upon the type of equipment (some may be verified daily and others annually).

Verification Observations/Documentation – Examples

System verification:

Receiving: The manager reviews temperature logs of refrigerated products at various intervals such as daily or weekly. An operation may want its HACCP Plan to specify that the manager checks the, monitoring records daily if:

- receiving constitutes a high volume, or
- products include particular items such as fresh tuna, mahi-mahi, mackerel, etc. (scombrotoxin-forming species).

Chill step: Weekly, the production manager checks the "chilling log" that is maintained for foods that are either left over or planned for later service. Recorded on the log sheet are the time the food is placed into the cooler, its temperature, the type of container used (depth per SOP), and measurements of the time and temperature involved in cooling the food.

Handwashing facilities and practices:

Daily, the manager checks the log maintained at the handwashing facilities and corrections made in areas where ready-to-eat food is prepared. Less frequent checks are made in other areas of the operation.

Process verification:

The manager checks daily or weekly, the time/temperature monitoring records at all CCPs (receiving, holding, preparation before cooking for scombrotoxin-forming seafood; cooking time/temp for hamburgers, etc.)

Procedural Step 7: Keep Records

In order to develop the most effective record keeping system for your operation, determine what documented information will assist you in managing the control of food safety hazards. Some recorded information should already be part of your food safety system, like shellfish tags, and an additional record may not be needed. Your record keeping system can use existing paperwork, such as delivery invoices, for documenting product temperature. Another method could be maintaining a log to record the temperatures. A record keeping system can be simple and needs to be designed to meet the needs of the individual establishment. It can be accomplished many different ways that are customized to your operation as long as it provides a system to determine that activities are performed according to the HACCP plan.

Accurate record keeping is an essential part of a successful HACCP program. Records provide documentation that the critical limits at each CCP were met or that appropriate corrective actions were taken when the limits were not met. Records also show that the actions performed were verified.

Involve your employees in the development of your management system. Ask them how they are currently monitoring CCPs. Discuss with them the types of corrective actions they take when a critical limit is not met. Employees are an important source for developing simple and effective record keeping procedures. Managers are responsible for designing the system, but effective day-to-day implementation involves every employee.

The simplest record keeping system that lends itself to integration into existing operations is always best. A simple yet effective system is easier to use and communicate to your employees.

Record keeping systems designed to document a process rather than product information may be more adaptable within a retail food establishment, especially if you frequently change items on your menu. Accurately documenting processes like cooking, cooling, and reheating, identified as CCPs, provides active managerial control of food safety hazards. Consistent process control by management reduces the risk of foodborne illness.

Simple logs for recording refrigeration eguipment temperature are perhaps the most common SOP records currently maintained. However, product temperature records are commonly CCP records.

Other records may include:

- writing the product temperature on delivery invoices,
- keeping a log of internal product temperatures of cooked foods, and
- holding shellstock tags for 90 days.

Some retail establishments have implemented comprehensive HACCP systems where records are maintained for each CCP. These records may be quality control logs; but, they can also constitute CCP records if they are designed to monitor activities that are, in fact, CCPs. The level of sophistication of record keeping is dependent upon the complexity of the food operation. For example, a cook-chill operation for a large institution would require more record keeping than a limited menu, cook-serve operation.

Once a specific process has been shown to work for you, such as an ice bath method for cooling certain foods, the frequency of record keeping may be reduced. In these instances, a record keeping system provides a scheduled check (verification) of the process to ensure that it effectively controls the risk factor. This approach is extremely effective for labor-intensive processes related to:

- cooking large volumes of food where a temperature check of each individual item is impractical,
- implementing a verified process will allow employees to complete the procedure within the course of a scheduled work day,
- cooling foods or leftovers at the end of the business day, or
- maintaining cold holding temperatures of ready-to-eat potentially hazardous foods in walk-in refrigeration units.

Procedural Step 8: Conduct Long-Term Verification

Once your food safety system is implemented, you will need to confirm that it is effective over time, an activity referred to in this document as long-term verification. You may benefit from both internal (quality control) verifications and external verifications that may involve assistance from the regulatory authority or consultants.

Long-term verification is conducted less frequently (e.g., yearly) than on-going verification. It is a review or audit of the plan to determine if:

- any new product/processes/menu items have been added to the menu,
- suppliers, customers, equipment, or facilities have changed,
- the SOPs are current and implemented,
- the worksheets are still current,
- the CCPs are still correct, or if new CCPs are needed,
- the critical limits:

  are set realistically and are adequate to control the hazard (e.g., the time needed to cook the turkey to meet the Food Code internal temperature requirement), and

- monitoring equipment has been calibrated as planned.

Long-term verification helps the operator:

- ensure the food safety management system is implemented and the HACCP plan is being followed
- improve the system and HACCP plan by identifying weaknesses
- eliminate unnecessary or ineffective controls
- determine if the HACCP plan needs to be modified or updated.

Prerequisite Programs

Food Code Interventions

The provisions of the Food Code provide a foundation on which to develop a food safety system based upon the principles of HACCP. Major interventions in the Food Code are demonstration of knowledge by the person-in-charge, employee health, no bare hand contact with ready-to-eat food, time and temperature control, and the use of a consumer advisory regarding the consumption of raw or undercooked animal foods. These interventions need to be addressed within the overall food safety program which may entail inclusion in SOPs. Refer to Chapters 2 and 3 of the Food Code for specific controls that need to be in place.

HACCP Prerequisites

Many provisions of the Food Code address the design of food establishments and equipment as well as acceptable operational practices. Adherence to design criteria and development of SOPs affect the food preparation environment. Both are considered prerequisite to the development of food safety systems based upon the HACCP principles. SOPs specify practices to address general hygiene and measures to prevent food from becoming contaminated due to various aspects of the food environment. When SOPs are in place, HACCP can be more effective because it can concentrate on the hazards associated with the food and its preparation and not on the food preparation facility.

Standard Operating Procedures (SOPs)

SOPs specific to your operation describe the activities necessary to complete tasks that accomplish compliance with the Food Code, are documented as a written reference, and are used to train the staff who are responsible for the tasks.

Three purposes for establishing SOPs for your operation are to protect your products from contamination from microbial, chemical, and physical hazards; to control microbial growth that can result from temperature abuse; and to ensure procedures are in place for maintaining equipment.

SOP procedures ensure that:

- product is purchased from approved suppliers/sources,
- the water in contact with food and food-contact surfaces and used in the manufacture of ice is potable,
- food-contact surfaces, including utensils are cleaned, sanitized, and maintained in good condition,
- uncleaned and nonsanitized surfaces of equipment and utensils do not contact raw or cooked ready-to-eat food,
- raw animal foods do not contaminate raw or cooked ready-to-eat food,
- toilet facilities are accessible and maintained,
- handwashing facilities are located in food preparation, food dispensing, warewashing areas, and immediately adjacent to toilet rooms and are equipped with hand cleaning preparations and single-service towels or acceptable hand drying devices,
- an effective pest control system is in place,
- toxic compounds are properly labeled, stored, and safely used,
- contaminants such as condensate, lubricants, pesticides, cleaning compounds, sanitizing agents, and additional toxic materials do not contact food, food packaging material, and food-contact surfaces, and
- food, food packaging materials, and food-contact surfaces do not come in contact with, and are not contaminated by physical hazards such as broken glass from light fixtures, jewelry, etc.

SOPs to Control Contamination of Food

Procedures must be in place to ensure that proper personnel health and hygienic practices are implemented including:

- restricting or excluding workers with certain symptoms such as, vomiting or diarrhea (see Food Code Chapter 2),
- practicing effective handwashing,
- restricting eating, smoking, and drinking in food preparation areas,

- using hair restraints,
- wearing clean clothing, and
- restricting the wearing of jewelry.

SOPs to Control Microbial Growth

These procedures ensure that all potentially hazardous food is received and stored at a refrigerated temperature of 41'F or below. Note that the Food Code makes some allowances for specific foods that may be received at higher temperatures refer to Chapter 3, Specifications for Receiving.

SOPs to Maintain Equipment

These procedures ensure that:

- temperature measuring devices (e.g., thermometer or temperature recording device) are calibrated regularly,
- cooking and hot holding equipment (grills, ovens, steam tables, conveyor cookers, etc.) are routinely checked, calibrated if necessary and are operating to ensure correct product temperature,
- cooling equipment (refrigerators, rapid chill units, freezers, salad bars, etc.) are routinely checked, calibrated if necessary and are operating to ensure correct product temperature, and
- warewashing equipment is operating according to manufacturer's specifications.

Glossary

As stated in the Purpose and Scope portion of Chapter 1, the Food Code definitions need to be used as a supplement to this Glossary. In some cases, this Glossary condenses those definitions for the purpose of this particular document.

Approved source means acceptable to the regulatory authority based on a determination of conformity with principles, practices, and generally recognized standards that protect public health.

Bacteria means living single-cell organisms. Bacteria can be carried by water, wind, insects, plants, animals, and people and survive well on skin and clothes and in human hair. They also thrive in scabs, scars, the mouth, nose, throat, intestines, and room temperature foods.

CCP means Critical Control Point.

Contamination means the unintended presence in food of potentially harmful substances, including microorganisms, chemicals, and physical objects.

Cross contamination means the transfer of harmful substances or disease-causing microorganisms to food by hands, food-contact surfaces, sponges, cloth towels and utensils that touch raw food, are not cleaned, and then touch ready-to-eat foods. Cross contamination can also occur when raw food touches or drips onto cooked or ready-to eat foods.

Corrective action means an activity that is taken by a person whenever a critical limit is not met.
Critical Control Point (CCP) means an operational step or procedure in a process, production method, or recipe, at which control can be applied to prevent, reduce, or eliminate a food safety hazard.

Critical Limit means a measurable limit at a CCP that can be monitored to control the identified hazard to a safe level in the food.

Fish.

a. means fresh or saltwater finfish, crustaceans and other forms of aquatic life (including alligator, frog, aquatic turtle, jellyfish, sea cucumber, and sea urchin and the roe of such animals) other than birds or mammals, and all mollusks, if such life is intended for human consumption.

b. includes an edible human food product derived in whole or in part from fish, including fish that have been processed in any manner.

Food means raw, cooked, or processed edible substance, ice, beverage, chewing gum, or ingredient used or intended for use or for sale in whole or in part for human consumption.

Food establishment means an operation at the retail level, i.e., that serves or offers food directly to the consumer and that, in some cases, includes a production, storage, or distributing operation that supplies the direct-to-consumer operation. Refer to Chapter 1, Defining Retail, for examples.

Foodborne Illness means sickness resulting from acquiring a disease that is carried or transmitted to humans by food containing harmful substances.

Foodborne outbreak means the occurrence of two or more people experiencing the same illness after eating the same food.

HACCP means Hazard Analysis Critical Control Points.

HACCP plan means a written document which is based on the principles of HACCP and which describes the procedures to be followed to ensure the control of a specific process or procedure.

HACCP system means the result of implementing the HACCP principles in an operation that has a foundational, comprehensive, prerequisite program in place. A HACCP system includes the HACCP plan and all SOPs.

Hazard means a biological, physical, or chemical property that may cause a food to be unsafe for human consumption.

Internal temperature means the temperature of the internal portion of a food product.

Meat means the flesh of animals used as food including the dressed flesh of cattle, swine, sheep, or goats and other edible animals, except fish, poultry, and wild game animals.

Microorganism means a form of life that can be seen only with a microscope; including bacteria, viruses, yeast, and single-celled animals.

Molluscan shellfish means any edible species of raw fresh or frozen oysters, clams, mussels, and scallops or edible portions thereof, except when the scallop product consists only of the shucked adductor muscle.

Monitoring means the act of observing and making measurements to help determine if critical limits are being met and maintained.

National Shellfish Sanitation Program (NSSP) means the voluntary system by which regulatory authorities for shellfish harvesting waters and shellfish processing and transportation and the shellfish industry implement specified controls to ensure that raw and frozen shellfish are safe for human consumption.

NSSP means National Shellfish Sanitation Program.

Operational step means an activity in a food establishment, such as receiving, storage, preparation, cooking, etc.
Parasite means an organism that grows, feeds, and is sheltered on or in a different organism and contributes to its host.

Pathogen means a microorganism (bacteria, parasites, viruses, or fungi) that is infectious and causes disease.

Personal hygiene means individual cleanliness and habits.

Potentially Hazardous Food.

> **Potentially hazardous food** means a food that is natural or synthetic and that requires temperature control because it is capable of supporting:
>
> a. the rapid and progressive growth of infectious or toxigenic microorganisms,
> b. the growth and toxin production of Clostridium botulinum, or
> c. in raw shell eggs, the growth of Salmonella Enteritidis.

Potentially hazardous food includes foods of animal origin that are raw or heat treated; foods of plant origin that are heat-treated or consists of raw seed sprouts; cut melons; and garlic and oil mixtures that are not acidified or otherwise modified at a processing plant in a way that results in mixtures that do not support growth of pathogenic microorganisms as described above.

Procedural step means an individual activity in applying this Guide to a food establishment's operations.

Process approach means a method of categorizing food operations into one of three modes:

a. Process number one: Food preparation with no cook step wherein ready-to-eat food is stored, prepared, and served;
b. Process number two: Food preparation for same day service wherein food is stored, prepared, cooked, and served; or

c. Process number three: Complex food preparation wherein food is stored, prepared, cooked, cooled, reheated, hot held, and served.

Ready-to-Eat Food.

> **Ready-to-eat** food means a food that is in a form that is edible without washing, cooking, or additional preparation by the food establishment or consumer and that is reasonably expected to be consumed in that form.
>
> **Ready-to-eat** food includes potentially hazardous food that has been cooked; raw, washed, cut fruits and vegetables; whole, raw, fruits and vegetables that are' presented for consumption without the need for further washing, such as at a buffet; and other food presented for consumption for which further washing or cooking is not required and from which rinds, peels, husks, or shells have been removed.

Record means a documentation of monitoring observation and verification activities.

Regulatory authority means a federal, state, local, or tribal enforcement body or authorized representative having jurisdiction over the food establishment.

Risk means an estimate of the likely occurrence of a hazard.

SOP means Standard Operating Procedure.

Shellfish means bi-valve molluscan shellfish.

Standard operating procedure (SOP) means a written method of controlling a practice in accordance with predetermined specifications to obtain a desired outcome.

Temperature measuring device means a thermometer, thermocouple, thermistor, or other device for measuring the temperature of food, air, or water.

Toxin means a poisonous substance that may be found in food.

Verification means the use of methods, procedures, or tests by supervisors, designated personnel, or regulators to determine if the food safety system based on the HACCP principles is working to control identified hazards or if modifications need to be made.

Virus means a protein-wrapped genetic material which is the smallest and simplest life form known, such as hepatitis A.

Resources and References

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FDA Publications and Federal Regulations

FDA Food Code, current edition, may be purchased from the U.S. Department of Commerce, National Technical Information Service, via telephone: (703) 487-4650 or via e-mail address: orders@ntis.fedworld.gov. The Code is also available electronically at: http://www.fda.gov.
Fish and Fishery Products - Code of Federal Regulations, Title 21, Part 123 Fish and Fishery Products.

Fish and Fishery Products Hazards and Controls Guide, Second Edition, January, 1998, Food and Drug Administration, Washington, D.C., may be purchased from:

National Technical Information Service
U.S. Department of Commerce
703-487-4650.

This Guide is also available electronically at: http://www.fda.gov. Select "foods," then select "seafood;" then select "HACCP."

Single copies may be obtained as long as supplies last from FDA district offices and from:

U.S. Food and Drug Administration
Office of Seafood
200 C St., S.W. Washington, D.C. 20204
202-418-3150.

National Shellfish Sanitation Program Guidelines for Control of Molluscan Shellfish, 1997 Revision, in press, may be purchased when printed from:

National Technical Information Service
U.S. Department of Commerce
703-487-4650.

USDA/FDA Foodborne Illness Education Information Center

The USDA/FDA Foodborne Illness Education Information Center provides information about foodborne illness prevention to educators, trainers, and organizations developing education and training materials for food workers and consumers. The center is part of an interagency agreement between the Food Safety and Inspection Service (FSIS) of the United States Department of Agriculture (USDA) and the Food and Drug Administration (FDA) of the United States Department of Health and Human Services. It is housed at the Food and Nutrition Information Center (FNIC) of the National Agricultural Library (NAL), USDA in Beltsville, Maryland. USDA and FDA established the center as part of a national compaign to reduce the risk of foodborne illness and to increase knowledge of food-related risks from production through consumption. The center's primary function is the development and maintenance of two databases.

The Foodborne Illness Educational Materials Database is a compilation of consumer and food worker educational materials developed by universities; private industry; and local, state, and federal agencies. This includes computer software, audiovisuals, posters, games, and teaching guides for elementary and

secondary school education; training materials for the management and workers of retail food markets, food service establishments, and institutions; educational research and more.

The Hazard Analysis Critical Points (HACCP) Training Programs and Resources Database provides up-to-date listings of HACCP training programs, HACCP resource materials, and HACCP consultants offering training programs or resources. Its intended users are educators, trainers, field staff in Extension, Food Safety and Inspection Service (FSIS) personnel, FDA personnel, private sector food processing plants and organizations, and others interested in identifying HACCP training resources.

You may access the databases or contribute materials through the Center's World Wide Web site at http://www.nal.usda.gov/fnic/foodborne/foodborn.htm. The online versions of the databases are searchable. Nonsearchable disk copies are available by writing to the address below. Resource lists of Food Safety and Risk Assessment and on Foodborne Pathogens are available on the web site under publications. The Center's web site also has a Food Safety Index with links to many other food safety materials.
For more information about the databases or to contribute materials and/or information, contact Cindy Roberts, Information Specialist, at:

USDA/FDA Foodborne Illness Education Information Center
National Agricultural Library/USDA
Beltsville, MD 20705-2351
Internet address: mailto:foodborne@nal.usda.gov

Annex 1 - Seafood Reference

Natural Toxins[1]

Natural Toxins	Type of Fish	Control
Paralytic Shellfish Poisoning (PSP)	Molluscan Shellfish N.E. and N.W coastal regions of N. America	NSSP approved waters (tags') (FDA ICSSL listing)
Neurotoxic Shellfish Poisoning (NSP)	Molluscan Shellfish harvested along coast of Gulf of Mexico	NSSP approved waters (tags) (FDA ICSSL listing)
Diarrhetic Shellfish Poisoning (DSP)	Molluscan Shellfish	NSSP approved waters (tags)2 (FDA ICSSL listing)
Amnesic Shellfish Poisoning (ASP)	Molluscan Shellfish N.E. & N.W coasts of N. America	NSSP approved waters (tagS)2 (FDA ICSSL listing)
Ciguatera Fish Poisoning (CFP)	fin fish from extreme S.E. U.S., Hawaii, Subtropical and Tropical areas: barracuda amberjack horse-eye jack black jack other larger species of jack king mackerel large groupers large snappers	Purchase from approved sources: ▪ get fish from areas that are not subject of a CFP advisory, or ▪ get fish from an area known by you or your supplier to be free of CFP problems
Gempylotoxin, a strong purgative oil (can cause severe diarrhea)	Escolar	FDA recommendation: Escolar should not be marketed in interstate commerce
Tetrodotoxin	Puffer Fish or Fugu, usually from Indo-Pacific ocean, however some noted from Atlantic Ocean, Gulf of Mexico and Gulf of California	Illegal to import or receive (exemption: an agreement with one N.Y. importer)

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[1] Fish & Fisheries Products Hazards & Controls Guide: Second Edition, January, 1998, Chapter 6

[2] The tags must contain a unique state issued "certification number' specific for each certified dealer. If the firm is engaged in interstate commerce, this number appears in FDA's Interstate Certified Shellfish Shippers List (ICSSL).

Fish Considered to be Scombrotoxin-Forming Species [3]

Toxin Information	Species – Market Names	Control
Scombrotoxin formation as a result of time temperature abuse	Most scombroid poisonings from tuna, mahi-mahi and bluefish. Other species are: Ambedack or yellowtail Anchovy Bluefish Bonito Escolar or Snake Mackerel Gernfish Herring (not River herring) Jack Jobfish Kahawai Mackerel (not Atka) Mahi-Mahi Marlin Pilchard or Sardine Sardine Saury Shad & roe Shad, Gizzard Snapper (Pristipornoides ssp) Sprat or Bristling Trevally Tuna Wahoo	Buy from approved federally inspected suppliers. They are required to receive, hold, and process using a HACCP system. Check for an adequate quantity of ice or other cooling media. If not, a federally inspected supplier or directly from a fishing boat, check for the following at receipt: - an adequate quantity of ice or other cooling media - the time the fish were caught (from the vessel or supplier) - internal temperatures of the fish expected for safety: * 5^{O}F (10^{O}C) or below if delivered 12 or more hours after death. * 40^{0}F (4.4^{0}C) or below if the fish are delivered 24 hours or more after death. - Control temperature after receipt Note following table for safe shelf-life time and temperature guidelines.

[3] Fish & Fisheries Products Hazards & Controls Guide: Second Edition, January, 1998, Chapter 7

Approximate Safe Shelf Life for Scombrotoxin-Forming Species at Various Storage Temperatures

Product Temperature	**Shelf Life (Days) with Rapid Cooling**	**Shelf Life (Days) with Delayed Cooling**
O F (-17.8 C)	No limit	No limit
32 F (0 C)	14	8
38 F (3.3 C)	10	7
40 F (4.4 C)	7	5
50 F (10 C)	3	0
70 F (21.1 C)	0	0
90 F (32.2 C)	0	0

'Fish & Fisheries Products Hazards & Controls Guide: Second Edition, January, 1998, Chapter 7

Parasites[4]

Parasites	Type of Fish Species Likely to be used in Menu Items that will not be Cooked	Control
nematodes or roundworm cestodes or tapeworms trematodes or flukes	Sea bass Capelin & roe Cod Flounder - Dab - Fluke Grouper Halibut Herring Jack Jobfish Kahawai Mackerel Monkfish Mullet Chilean Sea Bass Ocean Perch Plaice Pollock Rockfish Sablefish Salmon & roe (aquacultured and wild) Seatrout Sole Sprat/Bristling Trout/steelhead/rainbow Tuna, small Turbot Wolfish	Purchase from a processor, require the raw fish to have been frozen ▪ -4^{O}F (-20^{O}C) or below for 7 days Or ▪ -31 ^{O}F (-35^{O}C) or below for 15 hours Freezing can be done in your Operation if it is done in Accordance with the Food Code, Chapter 3

Some products that have been implicated in human infection are:

Ceviche	salmon roe	green herring	undercooked grilled fish
.lomi lomi	sashimi,	drunken crabs	
poisson cru	sushi	cold smoke fish	

[4] Fish & Fisheries Products Hazards & Controls Guide: Second Edition, January, 1998, Chapter 5

Annex 2 - Special Considerations Reference

I Foods that might be served raw or not cooked according to the Food Code
(Refer also to last page of Annex 1 for parasitic considerations for fish.)

Raw Animal Food	Menu Items	Hazards
Beef	Steak Tartare Carpaccio	Salmonellae Escherichia coli 01 57:H7
Poultry	Duck	Salmonellae Campylobacter jejuni
Finfish	Lightly cooked fish, sushi, raw-marinated, cold smoked fish Reef fish: (barracuda, amberjack, horse-eye jack, black/jack, other large species of jack, king mackerel, large groupers, large snappers)	Anisakis simplex Diphyllobothrium spp. Pseudoterranova decipiens Ciguatera toxin
Shellfish	Oysters Clams	Vibrio vulnificus Vibrio spp. hepatitis A Norwalk-like viruses
Eggs	Quiche, hollandaise sauce Eggs Benedict, mayonnaise, mousse, tiramisu, chicken croquettes, rice balls, stuffing, lasagna, french toast, chicken franchaise, crab cakes, egg nog, fish stuffing, Caesar salad, ice cream	Salmonella enteritidis Enteritidis

Foods that are a Concern Because of Emerging Issues

Food	Menu Items	Hazards
Produce	Tomatoes, sprouts, lettuce cantaloupe, raspberries, green salads, strawberries	Salmonellae, E. coli 01 57:H7, Shigellae, Cyclospora cayetanensis, hepatitis A, Norwalk like viruses
Juice	Apple juice/cider, other fruit or vegetable juices	Salmonellae, E. coli 0 157: HT Cryptosporidium parvum